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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,292	09/23/2004	Dimitrios T. Drivas	MP-01	3709

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HOXIE & ASSOCIATES LLC
75 MAIN STREET , SUITE 301
MILLBURN, NJ 07041

EXAMINER	
DAHLE, CHUN WU	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,292	DRIVAS, DIMITRIOS T.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *6-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on March 25, 2009, has been entered.

Claims 16-18 have been added.
Claims 1-18 are pending.

Claims 6 -15 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 7, 2006.

Claims 1-5 and newly added claims 16-18 are currently under consideration as they read on the elected invention of a method for treating a subject by generating an active immune response, asthma, SEQ ID NO:16 and Diphtheria toxoid (DT).

2. This Office Action is in response to Applicant's amendment to the claims and remarks filed on August 25, 2008 and March 25, 2009.

The rejections of record can be found in the previous Office Actions, mailed on May 29, 2007, February 25, 2008 and September 30, 2008.

3. The prior rejection under 35 U.S.C. 102(e) against claims 1-5 based upon Bachmann et al. (US 2003/0157479) (see Office Action mailed on May 29, 2008 and February 25, 2008) has been withdrawn (see Advisory Action mailed on September 30, 2008).

4. In view of applicant's amendment to the claims, the prior rejection under 35 U.S.C. 112, first paragraph, enablement against claims 1-5 has been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 and newly added claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Claims 1-5 and newly added claims 16-18 recite "a peptide comprising a 4 to 50 residue fragment of eotaxin" as part of the invention.

The disclosure of the instant specification is not sufficient to enable a skilled artisan to practice the claimed invention without conducting an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The limitation of "a peptide comprising a 4 to 50 residue fragment of eotaxin" raises issues regarding whether one of skill in the art would be able to make and use the claimed method encompassing administering such peptide fragment of eotaxin . The specification does not disclose which residues of the eotaxin must be retained for generating an active immune response. In turn, it would be undue burden for one of skill in the art to determine which 4 to 50 residues of the eotaxin are necessary to generate an active immune response in vivo. The

specification does not provide sufficient guidance regarding how to make and use a portion of eotaxin that is 4 to 50 residues of the eotaxin as claimed. Francis et al. (Current Opinion in Allergy and Clinical Immunology 2005. 5:537-543, reference of record), in addressing peptide-based vaccination, teach that peptides contain little or no secondary or tertiary structure compare to full length proteins; and in certain circumstance, peptides cannot generate specific antibodies against wild type proteins (see entire document, particularly left column on page 540). Further Francis et al. teach the selection of the appropriate peptides for use in immunotherapy remains a challenge (see left column on page 514, in particular)."

With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

7. Claims 1-5 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The phrase "a peptide comprising 4 to 50 residue fragment of eotaxin" recited in independent claim 1 is not supported by the original disclosure or claim as filed.

Applicant's amendment, filed on March 25, 2009, directs to support to pages 8 and 14 of the specification, and asserts that no new matter has been added.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitation". The specification does not provide sufficient support for "a peptide comprising 4 to 50 residue fragment of eotaxin". The specification only discloses eotaxin fragments with specific sequences (e.g. see SEQ ID NOs: 2-38 and 42-61); the instant

claims now recite "a peptide comprising 4 to 50 residue fragment of eotaxin", which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure (eotaxin fragment) and limited species of eotaxin fragments with defined amino acid sequences do not provide sufficient direction and guidance to the features currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-5 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renner et al. et al. (US Patent 7,320,793) in view of McDonell et al. (US Patent 6,416,763).

Renner et al. teach a method for treating human patients suffering from diseases including asthma by administering chemokines such as eotaxin vaccine wherein eotaxin is conjugated to an adjuvant to induce antibody response to eotaxin in human patients wherein the antibody response is sufficient to treat human disease (e.g. see columns 3-8 and 56-57).

The reference teachings differ from the claimed invention by not describing eotaxin that is bound to an immunogenic carriers, diphtheria toxoid, tetanus toxoid and keyhole limpet hemocyanin and vaccine adjuvant that is water-in-oil emulsion.

However, the use of carriers such as diphtheria toxoid, tetanus toxoid and keyhole limpet hemocyanin and water-in-oil emulsion adjuvant to enhance antibody production in vaccine composition were well known in the art at the time the invention was made. For example, McDonell et al. teach immunostimulating agents such as toxoid from diphtheria and tetanus can be conjugated to antigens and adjuvant to enhance effectiveness of the vaccine can be used in water-in-oil emulsion formulations (e.g. see columns 13 and 14).

It would thus be obvious to one of skill in the art at the time of the invention to combine the teachings of Renner et al. (regarding the method of treating asthma by administering eotaxin vaccine) with the teachings of McDonell et al. (with respect to the use of toxoid and vaccine adjuvant in water-in-oil formulation to enhance antibody production of vaccines) to enhance the effect of eotaxin in inducing antibody production in a method of treating asthma patients with eotaxin vaccine because all the claimed elements were known in the art and one of skilled artisan

could have combined the elements as claimed by known methods taught by McDonell et al. with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644